



IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of:

Barone, Jr. et al.

Serial No.: 10/775574

Filed: February 9, 2004

Atty. File No.: 5370-7

For: "COMPOSITIONS FOR
ENHANCING SEXUAL
RESPONSIVENESS"

) Group Art Unit: 1614

) Examiner:

SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

CERTIFICATE OF MAILING

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING
DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS
FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO
COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA VA
22313-1450, ON 17 June 2005.

SHERIDAN ROSS P.C.

BY: [Signature]

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The references cited on attached Form PTO-1449 are being called to the attention of the Examiner.

☒ Copies of the cited non-patent and/or foreign references are enclosed herewith.

☐ Copies of the cited U.S. patents and/or patent applications are enclosed herewith.

☒ Copies of the cited U.S. patents/patent application publications are not enclosed in accordance with the waivers dated July 11, 2003 and October 19, 2004, whereby patent applications filed, regardless of the filing date, need not submit copies of U.S. patents and U.S. patent application publications.

☐ Copies of the cited references are not enclosed, in accordance with 37 C.F.R. 1.98(d), because the references were cited by or submitted to the U.S. Patent and Trademark Office in prior application Serial No. _____ filed _____, which is relied upon for an earlier filing date under 35 U.S.C. § 120.

☐ To the best of applicants' belief, the pertinence of the foreign-language references are believed to be summarized in the attached English abstracts and in the figures, although applicants do not necessarily vouch for the accuracy of the translation.

☐ Examiner's attention is drawn to the following co-pending applications, copies of which have been or are being submitted:

Serial No. _____ filed _____

Serial No. _____ filed _____

☐ Other: _____

Submission of the above information is not intended as an admission that any item is citable under the statutes or rules to support a rejection, that any item disclosed represents analogous art, or that those skilled in the art would refer to or recognize the pertinence of any reference without the benefit of hindsight, nor should an inference be drawn as to the pertinence of the references based on the order in which they are presented. Submission of this statement should not be taken as an indication that a search has been conducted, or that no better art exists.

It is respectfully requested that the cited information be expressly considered during the prosecution of this application and the references made of record therein.

FEES

<input checked="" type="checkbox"/>	<p>37 CFR 1.97(b): No fee is believed due in connection with this submission, because the information disclosure statement submitted herewith is satisfies one of the following conditions ("X" indicates satisfaction):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d), or <input type="checkbox"/> Within three months of the date of entry into the national stage of an international application as set forth in 37 CFR 1.491 or <input checked="" type="checkbox"/> Before the mailing date of a first Office Action on the merits, or <input type="checkbox"/> Before the mailing of a first Office action after the filing of a request for continued examination under 37 CFR 1.114. <p>Although no fee is believed due, if any fee is deemed due in connection with this submission, please charge such fee to Deposit Account 19-1970.</p>
<input type="checkbox"/>	<p>37 CFR 1.97(c): The information disclosure statement transmitted herewith is being filed after all the above conditions (37 CFR 1.97(b)), but before the mailing date of one of the following conditions:</p> <ul style="list-style-type: none"> (1) a final action under 37 C.F.R. 1.113 or (2) a notice of allowance under 37 C.F.R. 1.311, or (3) an action that otherwise closes prosecution in the application. <p>This Information Disclosure Statement is accompanied by:</p> <ul style="list-style-type: none"> <input type="checkbox"/> A Certification (below) as specified by 37 C.F.R. 1.97(e). Although no fee is believed due, if any fee is deemed due in connection with this submission, please charge such fee to Deposit Account 19-1970. <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> <input type="checkbox"/> Please charge Deposit Account 19-1970 in the amount of \$180.00 for the fee set forth in 37 C.F.R. 1.17(p) for submission of an information disclosure statement. Please credit any overpayment or charge any underpayment to Deposit Account 19-1970.

<input type="checkbox"/>	<p>37 CFR 1.97(d): This Information Disclosure Statement is being submitted after the period specified in 37 CFR 1.97(c).</p> <p style="padding-left: 40px;"><input type="checkbox"/> This information Disclosure Statement includes a Certification (below) as specified by 37 C.F.R. 1.97(e) AND</p> <p style="padding-left: 40px;"><input type="checkbox"/> Applicants hereby requests consideration of the reference(s) disclosed herein. Please charge Deposit Account 19-1970 in the amount of \$180.00 under 37 C.F.R. 1.17(p). Please credit any overpayment or charge any underpayment to Deposit Account 19-1970. Election to pay the fee should not be taken as an indication that applicant(s) cannot execute a certification.</p>
--------------------------	---

Certification (37 C.F.R. 1.97(e))
(Applicable only if checked)

- ☐ The undersigned certifies that:
- ☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement. 37 C.F.R. 1.97(e)(1).
 - ☐ A copy of the communication from the foreign patent office is enclosed.
- OR
- ☒ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement. 37 C.F.R. 1.97(e)(2).

Respectfully submitted,

SHERIDAN ROSS P.C.

By: Robert D. Traver
Robert D. Traver
Registration No. 47,999
1560 Broadway, Suite 1200
Denver, Colorado 80202-5141
(303) 863-9700

Date: 17 JUNE 2005



Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT****Complete if Known**

Application Number	10/775574
Filing Date	February 9, 2004
First Named Inventor	Barone, Jr.
Art Unit	1614
Examiner Name	
Attorney Docket Number	5370-7

Sheet	1	of	4
-------	---	----	---

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-kind Code ^{2 (if known)}	Publication Date	Name of Patentee of Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	US-5,217,997	June 8, 1993	5,217,997	
	2.	US-5,232,935	August 3, 1993	5,232,935	
	3.	US-5,240,945	August 31, 1993	5,240,945	
	4.	US-5,318,960	June 7, 1994	5,318,960	
	5.	US-5,428,070	June 27, 1995	5,428,070	
	6.	US-5,451,407	September 19, 1995	5,451,407	
	7.	US-5,496,827	March 5, 1996	5,496,827	
	8.	US-5,543,430	August 6, 1996	5,543,430	
	9.	US-5,595,753	January 21, 1997	5,595,753	
	10.	US-5,767,160	June 16, 1998	5,767,160	
	11.	US-5,891,459	April 6, 1999	5,891,459	
	12.	US-5,895,658	April 20, 1999	5,895,658	
	13.	US-5,922,332	July 13, 1999	5,922,332	
	14.	US-5,985,860	November 16, 1999	5,985,860	
	15.	US-6,007,824	December 28, 1999	6,007,824	
	16.	US-6,117,872	September 12, 2000	6,117,872	
	17.	US-6,207,713	March 27, 2001	6,207,713	
	18.	US-6,294,517	September 25, 2001	6,294,517	
	19.	US-6,323,211	November 27, 2001	6,323,211	
	20.	US-6,368,640	April 9, 2002	6,368,640	
	21.	US-6,428,791	August 6, 2002	6,428,791	
	22.	US-6,476,037	November 5, 2002	6,476,037	
	23.	US-6,544,563	April 8, 2003	6,544,563	
	24.	US-6,548,087	April 15, 2003	6,548,087	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference is considered, whether or not citation is in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Complete if Known	
				Application Number	10/775574
				Filing Date	February 9, 2004
				First Named Inventor	Barone, Jr.
				Art Unit	1614
Examiner Name					
Sheet	2	of	4	Attorney Docket Number	5370-7

	25.	US-6,548,841	October 1, 2002	6,458,841	
	26.	US-6,579,543	June 17, 2003	6,579,543	
	27.	US-6,646,006	November 11, 2003	6,646,006	
	28.	US-2002-0151592	October 17, 2002	20020151592A2	
	29.	US-2002-0183297	December 5, 2002	20020183297A1	
	30.	US-2003-0077296	April 24, 2003	20030077296A1	
	31.	US-2004-0102358	May 27, 2004	20040102358A1	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ² ; Number ⁴ ; Kind Code ³ (if known)						
		PCT	-					
			-					
			-					
			-					
			-					
			-					
			-					

OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)		
Examiner Initials*	Cite No. ¹	
	32.	Burnett A.L., Chang, A.G., Crone, J.K., Huang, P.L., Sezen, S.F., Noncholinergic Penile Erection in Mice lacking the gene for endothelial nitric oxide synthase. J. Andrology 23(1):92-97 (2002).
	33.	Cellek S, Moncada S, Nitrgic neurotransmission mediates the non-adrenergic non-cholinergic responses in the clitoral corpus cavernosum of the rabbit. Br. J. Pharmacol. 125(8):1627-9 (1998).
	34.	Christianson DW, Arginase: structure, mechanism, and physiological role in male and female sexual arousal. Acc. Chem. Res. 38(3):191-201 (2005).
	35.	Elsner, P., Maibach, H.I. Cutaneous response to topical methyl nicotinate in human forearm and vulvar skin. J. Dermatol. Sci. 2(5):341-5 (1991).
	36.	Finnin, B., Transdermal Substance Delivery- What to Expect in the Near Future. Business Briefing: Pharmatech., pp. 192-193. (2003).

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference is considered, whether or not citation is in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Complete if Known	
				Application Number	10/775574
				Filing Date	February 9, 2004
				First Named Inventor	Barone, Jr.
				Art Unit	1614
				Examiner Name	
Sheet	3	of	4	Attorney Docket Number 5370-7	

37.	Gonzalez-Cadavid NF, Rajfer J, Therapy of erectile dysfunction. Endocrine 23(2-3):167-76 (2004).
38.	Gragasin FS, Michelakis ED, Hogan A, Moudgil R, Hashimoto K, Wu X, Bonnet S, Haromy A, Archer SL, The neurovascular mechanism of clitoral erection: nitric oxide and cGMP-stimulated activation of BKCa channels. FASEB J. 18(12):1382-91 (2004).
39.	Guy, RH, Maibach, HI., Rapid radial transport of methyl nicotinate in the dermis, Archives Dermatol. Res. 273:91-95 (1982).
40.	Irritants, Rubefacients and Vesicants, in Remington's Pharmaceutical Sciences 17th Edition, Mack Publishing Company, Eaton, Pennsylvania, p. 782, (1985).
41.	Ito TY, Trant AS, Polan ML., A double-blind placebo-controlled study of ArginMax, a nutritional supplement for enhancement of female sexual function. J. Sex Marital Ther. 27(5):541-9 (2001).
42.	Kim NN, Christianson DW, Traish AM, Role of arginase in the male and female sexual arousal response. J. Nutr. 134(10 Suppl):2873S-2879S; discussion 2895S (2004).
43.	Klotz, T. Mathers, M.J. Braun, M., Bloch, W., Englemann, U. Effectiveness of oral L-arginine in first-line treatment of erectile dysfunction in a controlled crossover study. Urol. Int. 63(4):220-23 (1999).
44.	Lebret, T, Herve JM, Gorny P, Worcel M, Botto H., Efficacy and safety of a novel combination of L-arginine glutamate and yohimbine hydrochloride: a new oral therapy for erectile dysfunction. Eur. Urol. 41(6):608-13; discussion 613 (2002).
45.	McKay, D., Nutrients and botanicals for erectile dysfunction: examining the evidence. Altern. Med. Rev. 9(1):4-16 (2004).
46.	Meston CM, Worcel M, The effects of yohimbine plus L-arginine glutamate on sexual arousal in postmenopausal women with sexual arousal disorder. Arch. Sex Behav. 31(4):323-32 (2002).
47.	Moncada S., Higgs EA. Molecular mechanisms and therapeutic strategies related to nitric oxide. FASEB 9:1319-1330 (1995).
48.	Muller, B., Kasper, M., Surber, C., Imanidis G., Permeation, metabolism and site of action concentration of nicotinic acid derivatives in human skin Correlation with topical pharmacological effect. Eu. J. Pharm. Sci. 20:181-95 (2003).
49.	Park JK, Kim SZ, Kim SH, Kim YG, Cho KW, Renin angiotensin system of rabbit clitoral cavernosum: interaction with nitric oxide. J. Urol. 164(2):556-61 (2000).
50.	Park JK, Kim JU, Lee SO, Hwang PH, Yi HK, Kim YG, Cho KW, Nitric oxide-cyclic GMP signaling pathway in the regulation of rabbit clitoral cavernosum tone. Exp. Biol. Med. 227(11):1022-30 (2002).
51.	Sample of CONNECTION™ packaging including ingredient list, enclosed herewith.
52.	Sivamani RK, Stoeber B, Wu GC, Zhai H, Liepmann D, Maibach H., Clinical microneedle injection of methyl nicotinate: stratum corneum penetration. Skin Res. Technol. 11(2):152-6 (2005).
53.	Stanislavov R, Nikolova V., Treatment of erectile dysfunction with pycnogenol and L-arginine. J. Sex Marital Ther. 29(3):207-13 (2003).

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference is considered, whether or not citation is in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Complete if Known	
				Application Number	10/775574
				Filing Date	February 9, 2004
				First Named Inventor	Barone, Jr.
				Art Unit	1614
Examiner Name					
Sheet	4	of	4	Attorney Docket Number	5370-7

	54.	Web page from the Better Business Bureau of Metropolitan New York, Inc., April 21, 2005.
	55.	Woolfson AD, Malcolm RK, Campbell K, Jones DS, Russell JA., Rheological, mechanical and membrane penetration properties of novel dual drug systems for percutaneous delivery. J Control Release. 3;67(2-3):395-408 (2000).

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference is considered, whether or not citation is in conformance and not considered. Include copy of this form with next communication to applicant.